

WE CLAIM:

1. In a bioassay for the detection in bodily fluids of teenage and adult humans of an antigen that is characteristic of a kind of bacteria causative of human ear and respiratory tract infections, which kind of bacteria also frequently colonizes the nasopharynx areas of children up to the age of about 12 years without infecting them,

the improvement in said bioassay for detection of said antigen in bodily fluid samples from said children up to the age of about 12 years which at least substantially reduces the incidence of false positive results stemming from nasopharyngeal colonization of otherwise healthy children, while maintaining the sensitivity of said bioassay to the presence of said antigen stemming from an infection and also maintaining the specificity of said bioassay at not less than 90%,

which improvement consists in reducing the total amount of antibodies to said antigen that are employed in each bioassay to a total amount less than that utilized in the otherwise identical bioassay employed in testing bodily fluids of teenage and adult humans, wherein the amount of reduction of total antibodies needed to obtain the stated results has been determined empirically in bioassay tests, wherein the total amount of antibodies present per test are varied, and the tests representing each variation are run identically on samples of bodily fluids taken from each of (1) otherwise healthy children known to have nasopharyngeal colonization by the bacteria of which the antigen is characteristic and (2) children known to have an ear or pneumococcal infection caused by the kind of bacteria of which the antigen is characteristic.

2. The improvement according to claim 1 wherein the antigen is characteristic of a kind of bacteria selected from among *Streptococcus pneumoniae*, nontypable *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Staphylococcus aureus*.

3. The improvement according to claim 2 wherein the antigen is a carbohydrate antigen characteristic of one of these bacteria.

4. The improvement according to claim 3 wherein the antigen is the polysaccharide antigen common to all serotypes of *Streptococcus pneumoniae*, and the kind of bacteria is *Streptococcus pneumoniae*.

5. The improvement according to claim 1 wherein the bioassay is an immunochromatographic assay.

6. The improvement according to claim 5 where the antibodies in each test are in part conjugated to a tag, in movable form, and in part immovably fixed on a capture line where tagged antibody-antigen-fixed antibody "sandwiches" form and mass at the conclusion of the bioassay.

7. The improvement according to claim 6 wherein the antibodies are antibodies to the polysaccharide antigen common to all serotypes of *Streptococcus pneumoniae* and the kind of bacteria is *Streptococcus pneumoniae*.

8. The improvement according to claim 6 wherein the amount of reduction of total antibodies needed to achieve the stated results has been empirically determined to be that attained (1) by conjugating a part of the antibodies to colloidal gold and making a conjugate solution having an optical density of 1.5 and (2) the concentration of antibody immovably fixed to the capture line is placed there from a solution containing 0.3 mg./ml. of antibody delivered

at a rate of 0.5 ml. per 6mm. of substrate by the delivery tip of a precision pump.

9. In an immunochromatographic ("ICT") bioassay for the detection in bodily fluids of teenage and adult humans of an antigen that is characteristic of a kind of bacteria causative of human ear and respiratory tract infections, which kind of bacteria also frequently colonizes the nasopharynx areas of children up to the age of about 12 years without infecting them,

the improvement in said bioassay for detection of said antigen in bodily fluid samples from said children up to the age of about 12 years which at least substantially reduces the incidence of false positive results stemming from nasopharyngeal colonization of otherwise healthy children, while maintaining the sensitivity of said bioassay to the presence in bodily fluids of said antigen stemming from an infection and also maintaining the specificity of said bioassay at not less than 90%,  
which improvement consists in adding at least one immovable "scrub" line located just prior to the capture line in the sample flow path of the ICT test strip to remove excess antigen by "scrubbing" out an identical portion thereof from samples of bodily fluid of each of (a) uninfected children who are colonized nasopharyngeally by the bacteria of which the antigen is characteristic and (b) persons who are infected by the same bacteria, wherein the number of capture lines, the concentration of antibody deposited on each capture line and the extent to which the concentration of antibodies otherwise employed in the test is modified, if at all, in order to obtain the stated results, have been determined empirically in bioassay tests wherein the number of "scrub" lines and the concentration of antibody on each "scrub" line and the concentration of antibodies

otherwise present per test are varied and tests representing each variation are run identically on samples of bodily fluids taken from each of (1) otherwise healthy children known to have nasopharyngeal colonization by the bacteria of which the antigen is characteristic and (2) children known to have an ear or pneumococcal infection caused by the kind of bacteria of which the antigen is characteristic.

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